

REMARKS

The Office Action dated August 24, 2005 has been carefully reviewed and the foregoing remarks are made in response thereto. In view of the above claim amendments and following remarks, Applicants respectfully request reconsideration and reexamination of this application and timely allowance of the pending claims.

By this Amendment, claims 1, 2, 6, 12, 25, 27 and 28 have been amended and new claims 42 to 53 have been added while the remaining claims have been cancelled without prejudice or disclaimer. Applicants submit that no new prohibited matter has been introduced by the amendments and that written support for the amendments can be found throughout the specification and in the original claims.

Summary of the Office Action

1. The specification was objected to for containing an imbedded hyperlink.
2. Claims 3, 4, 12, 27, 28 and 41 were objected to for containing non-elected subject matter, improper grammar or other informalities.
3. Claims 1 to 4, 6, 25 to 28 and 41 were rejected under 35 U.S.C. 112 (second paragraph) as being indefinite.
4. Claims 1 to 2, 4, 6 and 41 were rejected under 35 U.S.C. 112 (first paragraph) as containing subject matter which was not adequately described in the specification.
5. Claims 1 to 4, 6, 12, 28 and 41 were rejected under 35 U.S.C. 112 (first paragraph) for lack of enablement.
6. Claims 1 to 4, 12, 25 and 41 were rejected under 35 U.S.C. 102 as being anticipated by Lange *et al.*
7. Claims 1 to 4, 6, 12, 25 and 41 were rejected under 35 U.S.C. 103 as being unpatentable over Kurabayashi *et al.* and Carroll *et al.*
8. Claims 25 to 28 were rejected under 35 U.S.C. 103 as being unpatentable over Kurabayashi *et al.* and Carroll *et al.* in further view of Lin *et al.*

Objection to the Specification and Claims

Applicants have amended the specification to remove the imbedded hyperlink. Applicants have cancelled claims 3, 4 and 41 have been cancelled rendering the objection moot. Claim 12 has been amended to remove the non-elected subject matter and the objected language. Claims 27 and 28 have been

amended to correct the grammatical error. In view of these amendments, Applicants request withdrawal of the objections.

Rejections under 35 U.S.C. 112 (second paragraph)

Claims 1 to 4, 6, 25 to 28 and 41 were rejected under 35 U.S.C. 112 (second paragraph) as purportedly being indefinite. With regard to claim 1, Applicants submit that the claim as amended encompasses all types of radiation, but solely for the purpose of advancing prosecution and without acquiescing to the merits of the rejection, Applicants have amended the claim to add the term “ionizing” to the claims. Applicants also have amended claim 1 to remove the remaining language rejected by the Examiner and submit that the rejection is moot. With regard to claim 4, Applicants have cancelled this claim for the sole purpose of advancing prosecution and without acquiescing to the merits of the rejection, rendering this aspect of the rejection moot. With regard to claims 27 and 38, Applicants submit that the term “formulated for controlled release” is well known in the art based upon its plain meaning and that no clarification is required. Claim 3, 4 and 41 have been cancelled without prejudice or disclaimer rendering this aspect of the rejection moot. In view of these claim amendments, Applicants submit that the rejection is moot and request withdrawal of the rejection.

Rejections under 35 U.S.C. 112 (first paragraph)

Claims 1 to 2, 4, 6 and 41 were rejected under 35 U.S.C. 112 (first paragraph) as purportedly containing subject matter which was not adequately described in the specification. Without acquiescing to the merits of the rejection, claims 4 and 41 were cancelled, rendering this aspect of the rejection moot. With regard to claims 1, 2 and 6, Applicants have amended these claims without acquiescing to the merits of the rejection and solely for advancing prosecution. The amended claims now encompass a *Deinococcus* bacterium comprising a nucleic acid encoding the *mer* operon capable of detoxifying a heavy metal (*i.e.*, mercury). The Examiner purports that the specification only discloses a single species of *Deinococcus* transformed to express the proteins encoded by the *mer* operon (see Office Action at page 7). Applicants disagree and submit that the specification, which discloses multiple species of *Deinococcus* bacterium containing a *mer* operon (see, for example, page 20, lines 12 to 16 and page 21, lines 6 to 8), adequately discloses the subject matter of the claimed invention for purposes of the written description requirement.

Claims 1 to 4, 6, 12, 28 and 41 were rejected under 35 U.S.C. 112 (first paragraph) for lack of enablement. The Examiner purports that the specification, while being enabling for a radiation resistant

Deinococcus radiodurans transformed to express proteins encoded by the *mer* operon, does not reasonably provide enablement for any and all bacterium. Claim 41 has been cancelled without acquiescing to the merits of the rejection and for the sole purpose of advancing prosecution. Applicants bring to the attention of the Examiner that the same claims have been rejected for both being obvious and lacking enablement (claims 1 to 4, 6, 12). It is unclear to Applicants how the skilled artisan would find such claims lacking enablement if it would be obvious to the skilled artisan to reproduce the claims without undue experimentation. Applicants therefore request clarification from the Examiner regarding the rejections against these claims.

While Applicants disagree with the merits of the rejection, Applicants have nonetheless amended the claims to encompass a *Deinococcus* bacterium containing the *mer* operon for the sole purpose of advancing prosecution and without acquiescing to the merits of the rejection. Applicants submit that the specification adequately enables the amended claims and therefore the rejection is moot. Applicants bring to the attention of the Examiner that *Deinococcus* bacterium are naturally transformable, and therefore, the skilled artisan could readily transform the *mer* operon in any strain of *Deinococcus* without undue experimentation. To support this argument, Applicants attach a journal publication (Brim *et al.* (2003) Appl. Environ. Microbiol. (2003) 69, 4575-4582) by one of the the co-inventors which demonstrates similar results in another strain of *Deinococcus*, *Deinococcus geothermalis*. In view of the claim amendments and the above remarks, Applicants submit that the rejections are moot and request withdrawal of the rejection.

Rejection under 35 U.S.C. 102(a)

Claims 1 to 4, 12, 25 and 41 were rejected under 35 U.S.C. 102(a) as being anticipated by Lange *et al.* Applicants submit that the cited reference is not available as prior art in view of the attached declaration under 37 C.F.R. 1.131 from Dr. Michael J. Daly, a co-inventor of the present application and co-author of the cited reference. Although the authorship of the journal publication includes only two of the present inventors, the other authors on the journal publication were either working under that direction of the inventors, or derived their knowledge from the inventors of this application. Accordingly, the journal publication was not by “others” as required by 35 U.S.C. 102(a) and Applicants respectfully request that this rejection be withdrawn.

Rejections under 35 U.S.C. 103(a)

Claims 1 to 4, 6, 12, 25 and 41 were rejected under 35 U.S.C. 103 as being unpatentable over Kurabayashi *et al.* and Carroll *et al.* The Examiner purports that it would have been obvious to engineer a *Deinococcus radiodurans* of Carroll *et al.* to express proteins encoded by a *mer* operon disclosed by Kurabayashi *et al.* Without acquiescing to the merits of the rejection and solely for the purpose of advancing prosecution, Applicants have amended the claims to encompass a *Deinococcus* bacterium comprising a *mer* operon which grows in the continuous presence of ionizing radiation. Applicants first submit that the Examiner is using impermissible hindsight reasoning when combining the cited references. Neither of the cited references by itself discloses or suggests the elements of the amended claims (*i.e.*, a radiation resistant bacterium capable of reducing a heavy metal). Thus, no motivation to combine the cited references exists in the absence of the disclosure of Applicant's specification.

Second, Applicants bring to the attention of the Examiner that Carroll *et al.* does not disclose the growth of *Deinococcus* in the presence of continuous ionizing radiation, a feature of the amended claims. Rather the bacterium in that publication was exposed to intermittent radiation, bacterial growth was then measured after exposure, in the absence of radiation (see Figure 5 legend at page 133). It therefore appears that the Examiner has mischaracterized the cited reference when he stated that "Carroll *et al.* teaches how to express a heterologous protein in *D. radiodurans*, wherein the resulting protein can grow in the presence of 60 Gy/hour" (see Office Action at page 14). Bacterial growth in the cited reference was not measured during exposure to gamma radiation, but after exposure to radiation. Thus, it was not known, nor was it expected that *Deinococcus radiodurans* was capable of growing in an environment of continuous radiation exposure. In view of this feature of the amended claims, Applicants submit that there is no motivation to apply Carroll *et al.* In the absence of Carroll *et al.*, the primary reference, Kurabayashi *et al.* is also not applicable to the claimed invention because it does not disclose nor suggest a radiation resistant bacterium as set forth in the amended claims.

Third, Applicants bring to the attention of the Examiner that Carroll *et al.* discloses expression of a heterologous protein using an inducible promoter (see Figure 2 legend on page 132). The present invention encompasses a *Deinococcus* bacterium containing a *mer* operon with a constitutive promoter because the breakdown of heavy metals can only occur when the protein products of the *mer* operon are expressed. Inducible expression therefore does not have the same advantages of constitutive expression. The skilled artisan would readily recognize such advantages and therefore would not be motivated to apply

the disclosure of Carrol *et al.* to the claimed invention. In the absence of Carrol *et al.*, there would also be no motivation to apply the remaining reference.

Claims 25 to 28 were rejected under 35 U.S.C. 103(a) as being unpatentable over Kurabayashi *et al.* and Carroll *et al.* in further view of Lin *et al.* For the reasons discussed above, Applicants submit that the skilled artisan would not be motivated to apply Carrol *et al.* to the claimed invention. In the absence of Carrol *et al.*, there would also be no motivation to apply the remaining references. In view of the claim amendments and the above remarks, Applicants submit that the rejections are moot an request withdrawal of the rejections.

Conclusion


The foregoing amendments and remarks are being made to place the application in condition for allowance. Applicant respectfully requests reconsideration and entry of the amendments. A favorable action is awaited. Should the Examiner find that an interview would be helpful to further prosecution of this application, he is invited to telephone the undersigned at her convenience.

If there are any fees due in connection with the filing of this amendment, please charge the fees to our Deposit Account No. 50-310. If a fee is required for an extension of time under 37 C.F.R. 1.136 not accounted for above, such an extension is requested and the fee should also be charged to our Deposit Account.

Except for issue fees payable under 37 C.F.R. 1.18, the Commissioner is hereby authorized by this paper to charge any additional fees during the entire pendency of this application including fees due under 37 C.F.R. 1.16 and 1.17 which may be required, including any required extension of time fees, or credit any overpayment to Deposit Account 50-0310. This paragraph is intended to be a **constructive petition for extension of time** in accordance with 37 C.F.R. 1.136(a)(3).

Dated: **November 23, 2005**
Morgan, Lewis & Bockius LLP
Customer No. **09629**
1111 Pennsylvania Ave., N.W.
Washington, D.C. 20004
202-739-3000

Respectfully submitted
Morgan, Lewis & Bockius LLP



Robert Smyth
Registration No. 50,801